

### **REMARKS**

The Advisory Action of January 22, 2008 and the final Office Action of November 14, 2007 have been reviewed and the comments therein were carefully considered. Claims 1-48 are currently pending. Claims 1-11 and 27-38 have been withdrawn from consideration as being drawn to non-elected inventions. By this response, claims 12 and 21 have been amended. No new matter has been added.

#### **Claim Rejections Under 35 USC §103**

Claims 12-15, 17-26, 39-41, and 44-46 were rejected under 35 USC §103(a) as being unpatentable over Lebel, et al., U.S. Publication No. 2002/0016568 A1 ("Lebel"), in view of Mayer, U.S. Publication No. 2002/0010597 ("Mayer"). The Applicants respectfully disagree and traverse the rejection. Claim 12 has been amended to clarify that "the drug scheduling module receives data about the implantable drug delivery device, wherein the data is selected from the group consisting of drug usage information and drug management data." This amendment is supported by Figure 10 and paragraph 55 of the application as originally filed. Claim 21 has been amended to clarify a "scheduling module configured to calculate at least one relationship among the pump scheduling criteria, ~~other scheduling criteria~~, and monitored pump variables, the scheduling module configured to decide whether an appointment is required, and the scheduling module configured to activate the telemetry module to schedule an appointment." The feature of "other scheduling criteria" has been deleted and therefore the scheduling module is recited to calculate at least one relationship between the pump scheduling criteria and monitored pump variables. The amendment to claim 21 is supported by paragraph 55 of the application as originally filed.

Regarding amended claim 12, neither Lebel nor Mayer discloses a drug scheduling module that receives data about an implantable drug delivery device wherein the data is selected from the group consisting of drug usage information and drug management data, determines whether the drug should be replenished and initiates an appointment scheduling module for automatically, and without scheduling input contemporaneously provided by the patient,

scheduling an appointment to replenish the drug in the device. Lebel is directed to an implantable medical device and an external communication device that gives an alarm to a patient when the medication remaining in the implantable medical device becomes less than a predefined low-reservoir threshold. However, as recognized by the Examiner, Lebel does not disclose an appointment scheduling module initiated by a drug scheduling module. Further, the external communication device of Lebel is not an appointment scheduling module that is within the implantable drug delivery device as claimed in claim 12 of the present application.

Mayer does not remedy the deficiencies of Lebel. Mayer is directed to a set of software tools for a consumer to use for taking control of his or her own medical care. (See Abstract of Mayer). An appointment making tool is disclosed in paragraph 50 of Mayer: "This tool confirms, tracks and keeps appointments organized. For example, a patient needing an appointment for a physical." Thus, Mayer teaches appointment scheduling upon receiving a request from a patient for an appointment. While paragraph 50 of Mayer states that the appointment making tool "automatically requests an appointment and keeps track of scheduled appointments," there is no teaching or suggestion in Mayer that the scheduling of appointments is initiated by a drug scheduling module or any equivalent thereof. The Advisory Action contends that Mayer discloses an appointment scheduling module initiated by a drug scheduling module, indicating paragraph "39 of Mayer where the prompting of refills is disclosed." (See Continuation Sheet of the Advisory Action). Although a pharmacist tool is disclosed in paragraph 39 of Mayer to give "an estimation of compliance and can prompt for refills to improve compliance," there is no further disclosure with respect to prompting for refills, such as how the pharmacist tool could actually provide a prompt.

There is no teaching in Mayer that the pharmacist tool (paragraph 39) communicates in any way with the appointment making tool (paragraph 50). The Advisory Action appears to overlook that there is not even an implicit suggestion that the ability of the pharmacist tool to prompt for refills could be adapted to initiate the appointment making tool to automatically schedule an appointment. Indeed, paragraph 12 of Mayer states that "health care maintenance methodologies to date fail to provide individuals with the degree of control and direct involvement over one's own healthcare that can be provided from a patient-centric resource, and

paragraph 13 of Mayer states: "The present invention comprises a set of software tools that can be used by a consumer (patient or individual) to take charge of his or her own medical or health care. Systems and methods of the present invention enable a patient(s) to store, maintain and track his/her own medical data." See also the figures of Mayer, and paragraphs. 25, 30, 34, and 35 of Mayer which describe required patient input as shown in the figures of Mayer.

The visit report disclosed in paragraph 27 of Mayer requires input by a patient in order for the system to provide scheduling, prompting for and recordation of visit and follow-up visit reports. At best, automatic scheduling in Mayer is accomplished by scheduling input by the patient (paragraphs 50 and 27 of Mayer). Such scheduling is not the same as appointment scheduling initiated by a drug scheduling module that has received data about the implantable drug delivery device comprising drug usage information and/or drug management data and has determined that the drug should be replenished. Accordingly, there would have been no reason for one of ordinary skill in the art to remove the patient from involvement with the appointment making tool as disclosed in paragraph 50 of Mayer and configure the pharmacist tool as disclosed in paragraph 39 of Mayer to initiate the separate appointment making tool sans patient involvement.

Similar to Mayer, Lebel discloses a goal to "enhance user interface capabilities in ambulatory medical systems and in particular for implantable infusion pump systems." Lebel thus also states a concern for greater user involvement and again it would not have made sense to eliminate user interaction by employing automatic appointment scheduling. Consequently, without the benefit of the disclosure of the present invention, it would not have been obvious to one of ordinary skill in the art to provide an appointment scheduling module initiated by a drug scheduling module, as recited in the instant claims.

Neither Lebel nor Mayer discloses the features of amended claim 21. As discussed above, Lebel teaches an external device that sounds an alarm to remind the patient to schedule an appointment, and does not disclose a scheduling module that initiates a telemetry module to schedule an appointment. As discussed above, at best, the system of Mayer only schedules an appointment with scheduling input contemporaneously provided by the patient. There is no

teaching or suggestion by Mayer that an appointment may be scheduled by a scheduling module of an implantable drug delivery device that is configured to calculate at least one relationship among the pump scheduling criteria and monitored pump variables and which is configured to activate a telemetry module to schedule an appointment as claimed.

In sum, combining the features of Mayer with Lebel would not result in the embodiments recited in amended claims 12 or 21. Neither Lebel nor Mayer, alone or in combination, teach or suggest either an appointment scheduling module initiated by a drug scheduling module or a telemetry module initiated by scheduling module. Claims 13-15, 17-20 and 39-41 depend from claim 12 and claims 22-26 and 44-46 depend from claim 21, and are patentable over Lebel in view of Mayer for at least the same reasons as claims 12 and 21 and for the additional features recited therein.

Claim 16 was rejected under 35 USC §103(a) as being unpatentable over Lebel in view of Mayer, and further in view of Akers, et al., U.S. Patent No. 6,112,182 ("Akers"). Claim 16 depends from claim 12. Akers is directed to a data processing system for use in managing healthcare and does not remedy the deficiencies of Lebel and Mayer with respect to claim 12. Therefore claim 16 is patentable over Lebel in view of Mayer and further in view of Akers for at least the same reasons as claim 12, and for the additional features recited therein.

Claims 42-43 and 47-48 were rejected under 35 USC §103(a) as being unpatentable over Lebel in view of Mayer, and further in view of Cummings, Jr., et al., U.S. Patent No. 6,345,260 ("Cummings, Jr."). Claims 42-43 depend from claim 12 and claims 47-48 depend from claim 21. Cummings, Jr. is directed to an appointment scheduling interface for booking appointments with professionals. (See Col. 1, lines 13-16 of Cummings, Jr.) Cummings, Jr. does not remedy the deficiencies of Lebel and Mayer with respect to either claim 12 or amended claim 21. Cummings, Jr. does not teach or suggest at least an appointment scheduling module initiated by a drug scheduling module or a scheduling module that initiates a telemetry module to schedule an appointment. Rather, Cummings, Jr., discloses a

"[C]all center, to which clients can call through conventional telephone lines. (Col. 6, lines 46-47) "While client 10b is on the line, call center 11 can log onto the

Web from any Web browser. With proper security clearance and verification, server 15 permits access to online master schedule database 16, which contains and displays the appointment times and dates for all physicians on the system, i.e., showing those times when these physicians are willing to accept tentative appointment bookings.” (Col. 8, lines 1-7)

Appointment scheduling is therefore disclosed by Cummings, Jr. to be initiated by a *client call* to a call center.

Accordingly, none of Lebel, Mayer nor Cummings, Jr., either alone or in combination, teach or suggest the inventions of independent claims 12 or 21. Claims 42-43 depend from claim 12 and claims 47-48 depend from claim 21, and are patentable over Lebel in view of Mayer and Cummings, Jr. for at least the same reasons as claims 12 and 21 and for the additional features recited therein. Reconsideration and withdrawal of the 35 USC §103(a) rejections are respectfully requested.

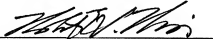
#### CONCLUSION

Applicants therefore respectfully request reconsideration of the pending claims and a finding of their allowability. A notice to this effect is respectfully requested. The Examiner is welcome to contact via telephone the undersigned should it be helpful to facilitate prosecution of the application.

Respectfully submitted,

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